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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,956

12/15/2005

Martin Hendrix

01-2113

1061

28519

7590

04/24/2009

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EXAMINER

MOORE, SUSANNA

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,956	<b>Applicant(s)</b> HENDRIX ET AL.	
	<b>Examiner</b> SUSANNA MOORE	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 4/3/2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/18/05</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Prosecution is reopened.**

Applicant's arguments, see Remarks, filed 4/3/2009, with respect to Office Action mailed 1/6/2009 have been fully considered. Some of the rejections have been withdrawn, others have been maintained, and some are new rejections or are new as a result of Applicant's amendments. Thus, this is a NonFinal Office Action. In summary, claims 1-5 and 8 are currently pending and under consideration.

### ***Claim Rejections - 35 USC § 112***

Claims 1-5 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compound of claim 1 or pharmaceutically acceptable salts of said compound does not reasonably provide enablement for a solvate of a compound of claim 1 is **withdrawn** based on the amendments.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et. al. (GB 973361).

The instant invention claims compounds of formula (I), wherein X= oxygen, R<sup>4</sup>= pentan-3-yl, R<sup>2</sup>= methyl and R<sup>3</sup>= hydrogen and R<sup>1</sup>= methyl.

The reference teaches compounds of formula (I), wherein X= oxygen, R<sup>4</sup>= sec-butyl, R<sup>2</sup>= methyl, R<sup>3</sup>= hydrogen and R<sup>1</sup>= methyl. See page 6, top left of page, and claims 1-8.

The difference between the reference and the instant Application is the substitution at the R<sup>4</sup> variable, sec-butyl versus Applicant's pentan-3-yl. There is an additional methyl group at the end of the methyl group of the sec-butyl group. Since a methyl group is considered a homolog of hydrogen these compounds are considered equivalent. The MPEP 2144.09 states "Compounds which are... homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH<sub>2</sub>- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re*

*Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). Thus, claims 1-5 and 8 are rendered obvious by Schmidt et. al.

Claims 1-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et. al. (DE 1156415).

The instant invention claims compounds of formula (I), wherein X= oxygen, R<sup>4</sup>= pentan-3-yl, R<sup>2</sup>= methyl and R<sup>3</sup>= hydrogen and R<sup>1</sup>= methyl.

The reference teaches compounds of formula (I), wherein X= oxygen, R<sup>4</sup>= isopropyl, R<sup>2</sup>= methyl, R<sup>3</sup>= hydrogen and R<sup>1</sup>= methyl. See page 6, lines 30-38, example 3.

The difference between the reference and the instant Application is the substitution at the R<sup>4</sup> variable, isopropyl versus Applicant's pentan-3-yl. The difference adds a methyl group to the end of the geminal methyl groups of the isopropyl group. The same homologue argument cited above applies here, too. Thus, claims 1-5 and 8 are rendered obvious by Schmidt et. al.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/  
Examiner, Art Unit 1624

/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624